Remarks

Reconsideration of pending Claims 24, 25, 27-33, 35-36, 38, 41-42, and 45-46 is respectfully requested.

Claims 24, 25, 27-33, 35-36, 38, 41-42, and 45-46 have been amended to clarify the invention as claimed. Claims 26 and 44 have been canceled.

Claims 24, 25, 35, 41, and 45 have been amended with the limitation recited in Claim 26 (now canceled) to define the concentration of the odorants in the recited composition. Claim 26 having been fully considered by the Examiner, no new matter has been added with this amendment to the claims.

Claims 35, 41, and 45 have also been reworded to eliminate redundancy in the claims.

Claim 41 has also been amended to limit the odorant composition as comprising a mixture of baby powder and chocolate odorants, to eliminate redundancy in view of Claims 35-36.

Claims 24, 35, 41, and 45 have been amended to eliminate the element of "instructions." As stated by the Examiner (at page 4), this limitation has not been given any patentable weight. Accordingly, the elimination of this element does not constitute new matter.

Claim 25 has also been amended to clarify that that the elements of "b)" are separately packaged elements, and are in the form of (i) a device for measuring blood flow to the vagina, (ii) a device for testing olfactory ability (i.e., the ability to identify a particular odor) — such as the UPSIT scratch-and-sniff identification test and the Chicago Smell Test (as described in the specification at page 5, lines 20-26 and page 7, lines 20-21), and/or (iii) a device for testing olfactory threshold (i.e., olfactory capacity, e.g., the magnitude of loss of smell) — such as a series of pyridine dilutions (as described in the specification at pages 5-6, bridging paragraph).

No new matter has been added with the amendments, which are intended to merely clarify language used in the claims and/or the subject matter claimed. The scope of the claims is intended to be the same after the amendment as it was before the amendment.

Rejections under 35 U.S.C. §112(2)

The Examiner rejected Claim 27 under Section 112(2) for the use of indefinite claim language. The Examiner maintains that the phrase "decismel units" is unclear in its meaning,

and requires a definition of this phrase within the specification or objective evidence of its meaning within the odorant/aroma art.

Claim 27 (as amended) recites as follows (emphasis added):

> 27. The article of manufacture of Claim 24, wherein the unit dosage amount of the odorant composition comprises a concentration of the odorant odorants at about **25 55 decismel units**.

The Examiner states that (Office Action at page 2):

> Claim 27 is rendered vague and indefinite by the phrase "decismel units." It is unclear as to what this phrase means - e.g., this unit of measure does not appear to be recognized in the odorant/aroma art, and there does not appear to be a reasonable definition of what this phrase means with respect to actual unit of measure. Is this attempting to define a measurement involving smell receptor units and/or olfactory concentration levels and if so, how is it actually measured." It is requested that Applicant particularly point to a definition of this phrase within the instant specification, or provide objective evidence as to its meaning - e.g., within the odorant/aroma art.

It is noted that the Examiner initially rejected Claim 27 for the use of the phrase **"decismel units"** in the Office Action mailed **September 24, 2001**, at page 5, as follows (emphasis added):

> Claim 27 is rendered vague and indefinite by the phrase "wherein the concentration of the odorant is at about **25-55 decismel units**" because it is unclear as to what this concentration relates to - e.g., is this the level of decismel units within each unit dosage or just a level of odorant in some initial odorant preparation from which such dosage units are prepared from?

As Applicant stated in the Response filed February 19, 2002,

> As stated in the specification at page 5, lines 4-7 (emphasis added):
> ...it is preferred that *the subject individual is presented with the odorant* at a superthreshold concentration (e.g., about 25-55 decismel units), but not irritative level,...

The term "decismel units" is an art-recognized term that is well understood by one of ordinary skill in the odorant arts. The Examiner is respectfully directed to the following patent and publication indicating the use and understanding of the term "decismels" as a concentration term.

> Amoore and O'Neill, *Proposal for a Unifying Scale to Express Olfactory Thresholds and Odor Levels: **the "Decismel Scale,"*** Olfacto-Labs, Berkeley, CA (1988), in Proceedings of the 1988 Air Pollution Control Association Annual Meeting, Paper No. 78.5 (21 pp.).

USP 5,492,934 (Hirsch) for "Chemosensory olfactory assay for somatization disorders" at col.

A patient is evaluated for a chemosensory dysfunction using standard chemosensory assays known to those of skill in the art. The patient's ability to detect the type and threshold amount of a chemosensory agent by the sense of taste or smell is measured. The preferred chemosensory assays include the Smell Identification Test™, the Accusens T™ Taste Test, and unilateral threshold tests. The unilateral threshold test can be conducted by standard methods and provides for olfactory testing with any number of chemosensory agents. **The standards for unilateral threshold testing in *decismels*, including the threshold concentrations for the chemosensory agents, can be obtained from OlfactoLabs, El Cerrito, Calif.**

...

The patient's threshold level for detecting a chemosensory agent is identified and compared to the known threshold values for the same sex and age group. **If the test samples containing a chemosensory agent are obtained from a commercial source, such as OlfactoLabs, El Cerrito, Calif., the samples are already calibrated in *decismels*** and no conversion from absolute threshold concentration to decismels is necessary....

Odor thresholds are expressed on the decismel scale. The decismel scale is constructed by setting the mean threshold concentration of a chemosensory agent detected by the control group of 20 year olds at the 0 value. A decismel is calculated by dividing the concentration of the chemosensory agent detected by the patient by the normal threshold concentration (using the published value or empirically determining the value) and then taking the logarithm of the quotient. The logarithm of the quotient is then multiplied by 20 to obtain the decismel value. Decismel values can be positive or negative. A positive decismel value indicates the patient is less sensitive to the chemosensory agent, i.e. has a higher threshold detection concentration. A negative decismel value indicates that the patient is more sensitive to the compound, i.e. has a lower threshold detection concentration. An increase in the threshold concentration value over the mean threshold concentration value of 2-fold, corresponds to 6 decismels (or ds).

See also, USP 5,380,765 (Hirsch) for "Chemosensory olfactory assay for psychiatric disorders."

Prudhomme et al., Acute-Onset Persistent Olfactory Deficit Resulting from Multiple Overexposures to Ammonia Vapor at Work, *J Am Board Fam Pract* 11(1):66-69 (1998)

Decismels (dS) are defined as 20 log (test concentration/reference concentration), where the reference concentration is the average odor threshold in a reference population. Thus, a score of 40 dS indicates that the patient's odor detection threshold was at a test concentration 100 times the population average for the compound employed.

Mergler et al., Olfactory threshold shift following controlled 7-hour exposure to toluene and/or xylene, *Neurotoxicology* 13(1):211-5 (1992)

...Olfactory perception thresholds, **measured in decismels (ds)**, were ascertained for both toluene and PM-carbinol, contained in 100 ml bottles with serially increasing concentrations (Olfacto-Lab Kits # 191 & 11)...

Sobell et al., Sniffing Longer rather than Stronger to Maintain Olfactory Detection Threshold, *Chem. Senses* 25: 1-8 (2000)

Monorhinal detection thresholds were determined using the two-alternative, forced-choice ascending staircase method (Cain et al., 1988). Threshold was determined as the lowest concentration at which five consecutive hits were achieved. The odorants vanillin and propionic acid were diluted in deionized water **on a decismel (DS) scale dilution series** [Odorant level in DS = 20log10 (test vapor concentration/reference concentration)] (Amoore, 1992), such that average detection threshold for 30 previously tested subjects = 0 DS. For each odorant, 24 dilutions were available, starting at –45 DS up to 65 DS (5 DS increments). In all measurements, a 40 s inter-trial-interval was used, and all experimental factors were randomized and counterbalanced.

U.S. Patent No. 6,324,475 (Hayes et al.) for "Devices for Presenting Airborne Materials to the Nose" (at col. 8, lines 56-64, col. 20, lines 62-65, (and elsewhere).

Each test substance/vehicle solution of interest is tested for its microdispensing performance in the test stand over a range of concentrations. For threshold testing of the sense of smell, 3-4 orders of magnitude dynamic range (**60-80 decismels**), where:

$$1 \text{ decismel} = \frac{\log 10 \text{ [odor concentration]}}{20}$$

USP 6,106,837 (Hirsch) for "Method of treating headaches, and article of manufacture therefor"

[Claim] 2. The method according to claim 1, wherein the concentration of the odorant is about 25-55 ***decismel*** units.

The method involves administering an effective concentration of a hedonically positive odorant ...Preferably, the subject individual is presented with the odorant at a suprathreshold concentration (e.g., about 25-55 decismel units)...

USP 5,904,916 (Hirsch) for "Use of odorants to alter learning capacity"

USP 5,885,614 (Hirsch) for "Use of odorants to treat male impotence, and article of manufacture therefor"

USP 5,759,521 (Hirsch) for "Method of altering perception of relative space of an area"

One skilled in the odorant arts would readily understand the term "decismel" as that term is used in the claims. Accordingly, it is submitted that the claims are clear in their meaning and satisfy the requirements of Section 112(2), and withdrawal of this rejection is respectfully requested.

Rejection of Claims under 35 U.S.C. 102(b)

The Examiner rejected Claims 24-30, 35, 36, 38,41, 42, and 44-46 as anticipated by the International Product Alert bulletin entitled "Poan Washable Cold Cream Manufacturere: Kurabara Honpo Category: Beauty Skin Care" (01 June 1994 - PROMT Abstract), or by McMath from Adweek's Marketing Week entitled "The Skin Trade Goes Natural" (27 August 1990 -PROMT Abstract). In the Office Action at page 7, the Examiner also rejected these claims as obvious over the same references. Insofar as these rejections are maintained with respect to the claims as amended, this rejection is respectfully traversed.

The Examiner cites the references as disclosing all of the elements of the claims. The Examiner maintains that the described cream products would inherently include cucumber and licorice extracts within the claimed odorant levels — a suprathreshold but not irritant amount of the odorants — on the basis that the cucumber extract and licorice extract would be at a level *detectable by a normosmic individual.*

First of all, a "suprathreshold" amount of an odorant is *not* the level detectable by a normosmic individual. Rather, it is the concentration of the odorant that is **beyond** that needed to be detected by a normosmic individual. This is stated in the specification at page 5, lines 1-19 (emphasis added):

> An odorant is presented at a suprathreshold level when the decismel level or concentration of the odorant *is beyond that needed to be detected by a normosmic individual*. At its irritative level, the odorant quantity is so high and intense that the odorant stimulates predominantly the trigeminal nerve (for pain) rather than the olfactory nerve and, hence, is perceived as noxious or painful. The irritation threshold of the patient is the lowest concentration of the substance that causes immediate stinging or burning sensations in the nose, or stinging or lacrimation of the eye. See, J.F. Gent, in Clinical Measurement of Taste and Smell, pages 107-166, H.L. Meiselman et al. (eds.), 602 pp., MacMillan, NY (1986); R.L. Doty et al., Ann. Neurol. 25: 166-171 (1989); E. Koss et al., Neurology 38: 1228-1232 (1988); and R. Doty, The Smell Identification Test: Administration Manual 1983: 13-14, Philadelphia: Sensonics, Inc. (1983).

The Examiner is also directed to USP 5,492,934 (Hirsch) for "Chemosensory olfactory assay for somatization disorders", which also states the understanding of a "suprathreshold amount" of a chemosensory agent at col. 5, lines 5-20 (emphasis added):

> ...The kit includes at least one chemosensory agent present in a variety of concentrations ranging from sub-threshold to suprathreshold amounts for that chemosensory agent. The normal or expected threshold concentration can be a known value published by Amoore et al., cited supra., or can be determined empirically by testing a group of normal individuals with a plurality of concentrations of the chemosensory agent and calculating the means threshold concentration...A sub-threshold amount is a concentration of the chemosensory agent below

> the normal or expected threshold concentration for that chemosensory agent. ***A suprathreshold amount is a concentration of the chemosensory agent greater than the threshold amount...***

First of all, the Examiner assumes that the described cream products have an odor. However, neither reference states anything about the vaporous emissions of the cream product.

Moreover, there is no teaching in either reference that either product contains a *suprathreshold amount* of a cucumber and licorice odorant — i.e., a concentration of the odorant that is beyond that needed to be detected by a normosmic individual. Nor is there any motivation for either product to be prepared with a suprathreshold amount (i.e., higher than normal amount) of an odorant as provided in Applicant's composition.

Applicant's compositions are formulated with a suprathreshold (but not irritant) amount of the recited odorants to achieve the intended effect (i.e., altering blood flow to the vagina).

The cream products described by the cited references would not inherently contain the odorants in a *suprathreshold amount* as recited in the claims.

Nor do the cited references teach a product containing a "unit dosage amount" of the odorant composition — i.e., an effective amount of odorant to alter (increase, decrease) blood flow to the vagina of a female individual.[1]

The Examiner also addressed the feature of "instructions" in the claims, which the Examiner has not given any patentable weight. Applicant submits that this feature is incidental to the claimed articles, and has eliminated the feature from the claims.

As for Claim 25, the element of "means for testing olfactory ability in the female individual" is separate and distinct from the element of a unit dosage amount of an odorant packaged in a container.

To clarify this element in the claims, Claim 25 has been amended to recite that this element is "a device for administering a plurality of odorants for testing olfactory ability of the female individual" (i.e., ability to identify an odorant). Such devices include, for example, a test

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[1] See the specification at page 7, lines 15-18 (emphasis added): "The odorant substance can be packaged as part of a kit in association with a container such as a vial, jar, pouch, bottle, cloth, aerosolizer, blister pack, and the like, that *holds an effective amount, or unit dosage amount, of the odorant to increase/decrease vaginal flow when administered to a female individual*;..."

such as the UPSIT scratch-and-sniff identification test, and the Chicago Smell Test, as described in the specification at page 5, lines 20-26 and page 7, lines 20-21, as follows (emphasis added):

> Preferably, prior to the administration of the odorant, the individual undergoes olfactory testing according to a test such as the *University of Pennsylvania Smell Identification Test (UPSIT), a 40-question forced-choice, scratch-and-sniff* ***identification test****, and the Chicago Smell Test, a 3-item detection and identification test* ...
>
> ...
>
> ...The kit can also include ***a substance and instructions for testing olfactory capacity for the presence and/or identity of an odorant***, and/or olfactory threshold.

Claim 25 has also been amended to recite that the article of manufacture can also include "a device for administering a series of odorants for testing olfactory threshold of the female individual" (i.e., olfactory capacity, e.g., magnitude of loss of smell). Such devices typically include, for example, a series of dilutions of an odorant substance such as butyl alcohol, pyridine, etc., combined in an odorless liquid, and a control stimulus, as described in the specification at pages 5-6, bridging paragraph, as follows (emphasis added):[2]

> The individual can also be evaluated for **olfactory capacity** (e.g. loss of smell) according to an **olfactory threshold test** as known and used in the art. Such a test provides a precise magnitude of loss of smell and classifies the individual as normosmic, hyposmic or anosmic, which is useful in assessing the effectiveness of a particular odorant and/or the required concentration of the odorant to provide a suprathreshold level to effectively reduce migrainous symptoms. According to that test, an odorant substance such as butyl alcohol, phenyl ethyl alcohol, or pyridine, is combined in an odorless liquid medium to provide a series of dilutions, or binary steps, of the odorant. For each successive binary step up the dilution scale, the odorant is present, for example, at one half the concentration of the preceding step. The highest concentration of the odorant usually provides the substance at an irritant level. The individual is presented with the series of dilutions in ascending order, and is asked to compare each dilution step to at least one control stimulus, such as odorless propylene glycol.
>
> ...
>
> ...The kit can also include ***a substance and instructions for testing*** olfactory capacity for the presence and/or identity of an odorant, and/or ***olfactory threshold.***

The cited references do not teach or suggest an article of manufacture containing the listed elements in combination as recited in Claim 25.

With regard to the Examiner obviousness rejection of the claims (at page 7), the Examiner maintains that it would be obvious "to provide such articles of manufacture" within a

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[2] See also, Amoore et al., *Practical Test Kits for Quantitatively Evaluating the Sense of Smell,* Rhinology 21: 49-51 (1983), describing a set of bottles containing serial dilutions of pyridine to quantitatively test olfactory threshold and sensitivity.

container or vessel. It is respectfully noted that it is the *odorant composition* that is packaged in a container, with Claim 25 reciting the combination of the contained odorant composition and other element(s) packaged together to form the article of manufacture. It is also noted that the references each describe the cream product in a container, with Poan describing the cream product contained in a jar, and McMath describing the cream product contained in a plastic tube.

The cited references do not teach or suggest an article of manufacture as claimed by Applicant comprising a unit dosage amount of a suprathreshold but not irritating concentration of an odorant composition to alter blood flow to the vagina when inhaled by a female individual. Nor do the references teach or suggest the combination of elements of the article of manufacture recited in Claim 25. Rather, the cited references merely teach a cream product that contains cucumber and licorice extracts in amounts to provide a moisturizing effect on the skin.

Accordingly, withdrawal of the rejection of the claims based on the cited references is respectfully requested.

Rejection of Claims under 35 U.S.C. 103(a)

The Examiner rejected Claims 24-33, 36, 38,41, 42, and 44 under Section 103(a) as obvious over the Drug & Cosmetic Industry (D&C.I.) publication entitled "Scentual Response" (Jan 1996, from PROMT database). This rejection is respectfully traversed.

The Examiner cites the publication as disclosing a report by the inventor, Dr. Alan Hirsch, that various odorants including a combination of lavender and pumpkin pie odorants caused increased penile blood flow.

Without admission and to expedite the present prosecution, the claims have been amended to eliminate a lavender and pumpkin pie odorant mixture. Accordingly, this rejection is considered mute.

The cited publication does not teach or suggest an article of manufacture in which the odorant composition is a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, or a mixture of baby powder and chocolate odorants, as claimed. Nor does the cited publication teach or suggest an article of manufacture as recited in Claim 25 composed of an odorant composition and the listed elements in combination.

Accordingly, withdrawal of this rejection is respectfully requested.

Double patenting.

The Examiner rejected Claims 24-33, 36, 38, 41, 42 and 44 on the basis of double patenting in view of Claims 22-23 of USP 5,885,614.

The basis of the Examiner's rejection of the claims is the recitation of a lavender and pumpkin pie odorant. The Examiner also maintains that the claimed odorants of USP '614 read upon a "means for testing olfactory ability" recited in Claim 25.

Without admission and to expedite the present prosecution, the claims have been amended to eliminate a lavender and pumpkin pie odorant mixture. Accordingly, this rejection is considered mute.

The cited publication does not teach or suggest an article of manufacture in which the odorant composition is a mixture of licorice-based and banana nut bread odorants, a mixture of licorice-based and cucumber odorants, or a mixture of baby powder and chocolate odorants, as claimed.

Further, as stated above with respect to Claim 25, the element of "means for testing olfactory ability in the female individual" recited in Claim 25 is separate and distinct from the element of a unit dosage amount of an odorant packaged in a container. Further, Claim 25 has been amended to recite that this element is "a device for administering a plurality of odorants for testing olfactory ability of the female individual," for example, a test such as the UPSIT scratch-and-sniff identification test, and the Chicago Smell Test. USP '614 does not teach or suggest an article of manufacture containing the listed elements in combination.

Accordingly, withdrawal of this rejection is respectfully requested.

Extension of Term. The proceedings herein are for a patent application and the provisions of 37 CFR § 1.136 apply. Applicant believes that a two (2) month extension of term is required, and hereby requests such extension and authorizes the extension fee to be charged to Account No. 23-2053. If any additional extension and/or fee are required, please consider this a petition therefore and charge the required fee(s) to Account No. 23-2053.

Applicant believes that the claims are in condition for allowance, and notification to that effect is respectfully requested. The Examiner is urged to telephone the undersigned Attorney if

any questions should arise or further discussion would expedite the examination of the application.

Respectfully submitted,

Dated: November 1, 2004

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